UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,194	12/04/1998	MANFRED BOHN	02481.1596	5713

22852 7590 01/25/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
EPPERSON, JON D	
ART UNIT	PAPER NUMBER
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/077,194	BOHN ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-42,48 and 61-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-42, 48 and 61-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. The Response filed September 22, 2006 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 38-42, 48 and 53-67 were currently pending. Applicants An action on the merit follows. Applicants canceled claim 53-60 and 67 in their 7/17/06 Response. In addition, Applicants further amended claims 38, 39, 42, and 61-66. Therefore, claims 38-42, 48 and 61-66 are currently pending and examined on the merits.

Withdrawn Objections/Rejections

4. The 35 U.S.C. § 112, second paragraph rejection denoted "A" is withdrawn in part in view of Applicants' amendments to claim 38. The Lagarde rejection under 35 U.S.C. § 102 is hereby withdrawn in part in view of Applicants' cancellation of claim 67. The Lange rejection under 35 U.S.C. § 102 is hereby withdrawn in part in view of Applicants' cancellation of claim 67. The Lagarde rejection under 35 U.S.C. § 103(a) is withdrawn in view of Applicant's cancellation of claims 59, 60 and 67. The Lange rejection under 35 U.S.C. § 103(a) is withdrawn in view of Applicant's cancellation of claims 59, 60 and 67. The provisional double patenting rejection is withdrawn in part in view of Applicants' cancellation of claims 53-60 and

67. All other rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claims Rejections - 35 U.S.C. 112, first paragraph

5. Claims 38, 40, 41, 42, 48 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

A. Claims 38 was amended in 2/22/05 response to recite "... administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising: (A) a sole active component consisting of at least one 1-hydroxyl-2-pyridone of formula I ... in free form or as a pharmaceutically acceptable salt ... wherein the composition has a pH ranging from about 4.5 to about 6.4" in lines 3-5 and the last line of the claim. However, the Examiner cannot find support for this claim limitation with regard to the "pharmaceutically acceptable salt" embodiment. For example, Applicants' specification states, "... when using the compounds in salt form, the adjustment of the pH range mentioned has to be carried out using organic acids" (e.g., see specification, page 8, lines 30-32; see also Example 7 wherein "lactic acid" is used to adjust the pH). Furthermore, organic acids, including lactic acid, are known to possess anti microbial action (e.g., see Lange, page 7, last paragraph, "... acids per se possess an antimicrobial action, such as fumaric acid and azelaic acid. In this way the effect of the antimycotic in phase I as well as phase II is enhanced!"; see also paragraph bridging pages 9-10,

"Examples of these acids are ... lactic"). Applicants have not shown where support for this new genus of compounds that contains "1-hydroxyl-2-pyridone of formula I salt + "non-active" organic acids" can be found. If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found in accordance with MPEP 714.02. Therefore, claim 38 and all dependent claims represent new matter.

Response

6. Applicant's arguments directed to the above New Matter rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection may been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "It is the applicant's understanding that lactic acid is not active in the treatment of seborrheic dermatitis, but rather is used as a pH adjuster. The specification" (e.g., see 7/17/06 Response, page 8, last paragraph)

[1] Applicants' arguments do not rise to the level of factual evidence. See MPEP § 716.01(c): The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

[2] Applicants argue, "the Examiner has not established that lactic acid would be active in the treatment of seborrheic dermatitis." (e.g., see 7/17/06 Response, page 8, last paragraph).

[2] The Examiner respectfully disagrees. Lange states on page 7, last paragraph, ". . . acids *per se* possess an antimicrobial action, such as fumaric acid and azelaic acid. In this way the effect of the antimycotic in phase I as well as phase II is enhanced!" (see also paragraph bridging pages 9-10, Examples of these acids are ... lactic"). Thus, an acid like lactic acid "per se" enhances "antimycotic" action, which would include the treatment of seborrheic dermatitis because it is caused by the yeast *Malassezia furfur* (formerly known as *Pityrosporum ovale*) (see Wikipedia, the Free Encyclopedia. Seborrhoeic dermatitis. Retrieved at http://en.wikipedia.org/wiki/Seborrheic on January 20, 2007, page 1 of 2; see also Wikipedia, the Free Encyclopedia. Fungus. Retrieved at http://en.wikipedia.org/wiki/Fungus on January 20, 2007, pages 1-7, disclosing that a yeast falls within the class of a fungus), which is susceptible to antimycotics (e.g., see Applicants' specification, page 1, last two paragraphs, "The most promising type of treatment of seborrheic dermatitis until now was the topical application of corticosteroid preparations, but more recently topical therapy with antimycotic substances has gained importance ... the antimycotic substances such as ketoconazole are active exclusively against the yeast fungi of the strain Pityrosporum which is assumed to be the cause of seborrheic dermatitis.").

Accordingly, the New Matter rejection cited above is hereby maintained.

Claims Rejections - 35 U.S.C. 112, second paragraph

7. Claims 38-42, 48 and 61-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claim 38**, the "pharmaceutically acceptable salt" embodiment requires two active ingredients, (1) the salt of a compound of formula I and (2) the organic acid that is used to adjust the pH (e.g., see specification, page 8, lines 30-32, "... when using the compounds in salt form, the adjustment of the pH range mentioned has to be carried out using organic acids"; see also Example 7 wherein "lactic acid" is used to adjust the pH; see especially dependent claim 65 wherein "lactic acid" is specifically required by the claims, which further limits independent claim 38) and, as a result, the claim cannot be limited to a "sole" active ingredient. For example, organic acids, including lactic acid, are known to possess anti microbial action (e.g., see Lange, page 7, last paragraph, "... acids per se possess an antimicrobial action"; see also paragraph bridging pages 9-10, "Examples of these acids are ... lactic"; see especially, page 15, second set of ingredients, "lactic acid ... (bacterio and mycostatic agent)"). Thus, it is not clear how the composition comprises a "sole" active ingredients when more than one active ingredients are being claimed (e.g., formula I salt + lactic acid). Consequently, the metes and bound of the claimed invention cannot be determined. Therefore, claim 38 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

B. For **claims 38-42, 48, 53, 55-59, 61-67**, the term "seborrheic dermatitis" is vague and indefinite in view of the prosecution history. For example, Applicants state, "Dascalu et al. misuses dermatology nomenclature by confusing 'dandruff' with 'seborrheic dermatitis' ... Although seborrheic dermatitis involving the scalp may give rise to a mistaken diagnosis of dandruff, it is well understood in the field of dermatology that seborrheic dermatitis is a condition distinct from dandruff" (e.g., see 4/24/02

response, pages 19-20). Applicants define "seborrheic dermatitis" as "a disorder of the scalp which differs from simple dandruff by the presence of erythema as a sign of inflammation, by the greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes to other body sites" (e.g., see specification, page 1). Applicants further state, "Pityrosporum ... is assumed to be the cause of seborrheic dermatitis" (e.g., see specification, page 1, last paragraph). However, Dascalu et al. disclose a treatment for the exact same symptoms as those defined in Applicants' specification (e.g., see Dascalu et al., line 12 wherein inflammation is disclosed; see also page 5, Table 1, patient 5, wherein a high degree of scaling is disclosed; see also page 5, Table 1, patient 2 wherein a high degree of "itching" is disclosed; see also Table 5, patient 5 wherein the overall severity of the dandruff is characterized as "severe" or, in Applicants' words, not just "simple dandruff"). In addition, Dascalu et al. explicitly state that their treatment inhibits the exact yeast, Pityrosporum (e.g., see Dascalu et al., line 13; see also claim 8). Thus, it is not clear what symptoms, underlying causative agents and/or other physiochemical factors Applicants are relying on to make this distinction (i.e., there is no basis for this assertion). Thus, the metes and bound of the claimed invention cannot be determined. Therefore, claims 38-42, 48, 53, 55-59, 61-67 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Response

8. Applicant's arguments directed to the above 35 U.S.C. 112, second paragraph rejections were fully considered (and are incorporated in their entirety herein by reference) but were not

deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or newly amended arguments.

A. Applicants argue, "With respect to claim 38, the Examiner rejected the claim as indefinite for the same reasons explained in the written description rejection discussed earlier Applicants respectfully traverse the rejection in that regard for the same reasons discussed above." (e.g., see 7/17/06 Response, page 9, paragraphs 1 and 2).

This is not found persuasive for the following reasons:

A. To the extent that Applicants are merely repeating their previous arguments with regard to the 35 U.S.C. § 112, first paragraph rejection, the Examiner contends that those issues were adequately addressed in the above sections, which are incorporated in their entireties herein by reference.

B. Applicants argue that the term seborrheic dermatitis is well defined in view of the specification at page 1, lines 3-11 and in further view of the American Academy of Dermatology submission (AAD) (e.g., see 7/17/06 Response, pages 9 and 10).

This is not found persuasive for the following reasons:

B. The Examiner respectfully disagrees. While these definitions may or may not be clear, Applicants' "use" of the term in their prosecution history certainly is not. As previously mentioned, Dascalu et al. disclose a treatment for the exact same symptoms as those defined in Applicants' specification including page 1, lines 3-11. In addition, Dascalu et al. explicitly state

that their treatment inhibits the exact yeast, Pityrosporum (e.g., see Dascalu et al., line 13; see also claim 8). Thus, it is not clear what symptoms, underlying causative agents and/or other physiochemical factors Applicants were relying on to make this distinction (i.e., there is no basis for this assertion). Since Applicants' failed to address the Dascalu et al. reference, the rejection is hereby maintained. In sum, it is unclear whether the specification, AAD reference, prosecution history, the Todd Plott declaration and brochure, Mitchel S. Wortzman declaration and corresponding exhibits (e.g., see 9/22/06 Supplemental Response) or some combination of these provides the correct definition for the term. In addition, Janniger et al. refutes Applicants' position that Seborrheic Dermatitis has a well defined meaning separate from "dandruff" stating, "In adolescents and adults, seborrheic dermatitis commonly is manifested as 'dandruff' or as an erythema of the nasolabial fold, ranging in intensity from barely perceptible to marked" (e.g., see Janniger et al., page 149, column 1, paragraph 1; see also abstract, "Seborrheic dermatitis is a common condition that usually appears as simple dandruff"). Thus, the definition in the literature is at best ambiguous as well.

Accordingly, the 35 U.S.C. 112, second paragraph rejections cited above are hereby maintained.

Claims Rejections - 35 U.S.C. 102

9. Claims 39 and 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Lagarde (WO 96/02226) (Date of patent is **February 1, 1996**) (translation provided) as evidenced by Wikipedia (e.g., Wikipedia, "Category: Surfactants" last modified 24 November 2005, page 1, accessed on 12/3/05 at http://en.wikipedia.org/wiki/Category:Surfactants).

For ***claims 39, 62 and 63***, Lagarde et al. (see entire document) disclose a novel combination product comprising an anti-fungal agent selected from the 1-hydroxyl-2-pyridones such as circlpirox or octopirox and, secondly, crotamiton as an antifungal agent activity enhancer (e.g., see Lagarde et al., abstract), which anticipates the claimed invention. For example, Lagarde et al. discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said combination (e.g., see page 5, middle paragraph, "Moreover, seborrheic dermatitis is more common in patients that have atopical background, cervico-cephalic atopical dermatitis, with the presence of orbicular anti-pitysrosporum specific Ig E in which the rate is highly correlated with the severity of the disease. With respect to dermatophytoses we can mention athlete's foot, scalp disease as well as all cases of onychomycosis. Given all of these pathologies, few therapies are actually effective"; see also page 6, paragraphs 3 and 4, "Therefore there is a real need for an anti-fungal product that would have different qualities ... the present invention deals with a new combination product, in which the synergistic combination offers improved anti-fungal activity"). In addition, Lagarde et al. discloses at least one 1-hydroxyl-2-pyridone of formula I as the sole active component (e.g., page 7 of the translation formula (I); see especially see page 9, first full paragraph, wherein ciclopirox (R1=cyclohexyl, R2=R4=H and R3=CH3) or octopirox (R1=2,4,4-trimethylpentyl, R2=R4=H and R3=CH3) are disclosed). Furthermore, Lagarde et al. discloses, for example, the use of a surfactant (e.g., see page 16 of the translation, last paragraph, "It is quite evident that these formulas are not limiting and that it is important to make certain of the compatibility of surface-active agents with the combination 1-hydroxy-2-pyridone

/crotamiton according to the invention; see also Examples wherein surfactants like Cocamide DEA, Cocamide MEA, Cocamidopropyl betaine are disclosed). Lagarde et al. do not state that Cocamide DEA (non-ionic), Cocamide MEA (non-ionic), Cocamidopropyl betaine (amphoteric) are "surfactants", but the Examiner contends that these would be inherent properties of these molecules as exemplified by Wikipedia (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant ... which is included as a foaming agent ... in a huge variety of commonly used products ... shampoos").

For ***claim 61***, Lagarde et al. disclose the cyclohexyl R4 group (e.g., see page 9, first full paragraph, wherein ciclopirox (R1=cyclohexyl, R2=R4=H and R3=CH3) or octopirox (R1=2,4,4-trimethylpentyl, R2=R4=H and R3=CH3) are disclosed).

For ***claim 64***, Lagarde et al. discloses at least one "additional" surfactant such as cocamidopropyl betaine + Cocamide MEA. (e.g., see Example 4).

Response

10. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "[t]he method of independent claim 39 has now been amended to recite administering a composition comprising a sole active component, which is a 1-hydroxy- 2-

pyridone of formula I or a pharmaceutically acceptable salt thereof. As mentioned by the Examiner on page 7 of the Office Action, Legarde teaches the use of a combination product comprising two active components: an anti-fungal agent and crotamiton. Under 35 U.S.C. § 102(b), Lagarde must include all of the elements of Applicants' claim to be anticipatory. Lagarde requires that his composition be a "combination product" that benefits from "the said synergic association of products [the 1 -hydroxy-2-pyridones and crotamiton]." (Lagarde translation, page 6.) Applicants' claims each require that the sole active component is the specified 1-hydroxy-2-pyridone, and none of the claimed compositions may be 'combination products.' Lagarde does not teach non-combination products nor the use of 1-hydroxy-2-pyridones by themselves as active compounds. Indeed, Lagarde teaches away from this. Therefore, Applicants request that this rejection be withdrawn." (e.g., see 7/17/06 Response, page 10).

[1] The Examiner respectfully disagrees. Applicants' claims encompass more than just one active ingredient (e.g., see 35 U.S.C. § 112, second paragraph) and, as a result, Applicants' arguments are moot.

[2] Applicants argue that the Wikipedia reference is "unreliable" and cite several sources in support of this argument (e.g., see 7/17/06 Response, page 11).

[2] All sources of information are susceptible to mistakes. While Applicants point to potential mistakes with the Kennedy assassination, etc., no such evidence has been provided to show that the "surfactants" entry has been similarly maligned. Furthermore, Wikipedia is Justas reliable as other more traditionally sources of information like Britannica. For example, the scientific journal nature, perhaps one of the most highly respected journals in the world, did a

study comparing the reliability of Wikipedia to Britannica and concluded that the difference in reliability was "not particularly great" (See Study: Wikipedia as Reliable as Britannica, Get It? Online Communication and more, December 15, 2005, page 1 of 2, visited on January 21, 2007 at http://www.henrikharsbo.dk/getit/2005/12/study_wikipedia.html). If Applicants take issues with its teaching then Applicants should present references of their own to show the inconsistencies with the "surfactant" entry. This has not been done. Therefore, Applicants' arguments are moot.

Accordingly, the 35 U.S.C. § 102 rejection cited above is hereby maintained.

11. Claims 39 and 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Lange (WO 88/00041) (Date of Patent is **14 January 1988**) as evidenced by Green People (Green People, "Sodium Laurel Sulphate", **2002**, page 1, accessed on 12/3/05 at http://www.greenpeople.co.uk/Organics_Features_SLS.htm) and Avre Skin Care (Avre Skin Care, "Dermatology Dictionary", **2002**, pages 1 and 10, accessed on 12/3/05 at http://www.avro.co.za/misc/about_skincare/cosmetic_ingredients.html).

For ***claims 39, 62 and 63***, Lange (see entire document) discloses a two phase cleansing, conditioning and medicinal treatment shampoo and methods of use (e.g., see Lange, abstract), which anticipates the claimed invention. For example, Lange discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said shampoo (e.g., see page 12, Example 1, "Shampoo for psoriasis-like seborrhoic dermatitis"; see also page 13, paragraph 1, "The test persons were persons suffering from tenacious dandruff, while one of them suffered from a grave seborrhoeic dermatitis"; see

also page 11, first full paragraph, "One may also use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "***The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant*** ... In a specific embodiment ***one may use a water soluble anti-mycotic such as piroctone olamine (Hoechset)***, chemical name 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone"). In addition, Lange discloses at least one 1-hydroxyl-2-pyridone of formula I as the active component (e.g., see Example 2, especially page 16, paragraph 2 wherein piroctone olamine is substituted for zinc pyrithion as the sole anti-mycotic; see also page 11, first full paragraph; see also page 13, first full paragraph, "One may also [i.e., in addition to phase I] use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics [i.e., piroctone olamine is an anti-mycotic] in the medicinal as well as the anti-dandruff variant ... In a specific embodiment one may use a water soluble anti-mycotic such as piroctone olamine"; see also page 16, first full paragraph, "Similar or even better results were obtained when substituting piroctone olamine for zinc pyrithion [which refers to the "phase I" ingredients of Example 2 i.e., the phase II ingredient don't contain zinc pyrithion for such a substitution to occur]"; see also page 8, last paragraph). The active ingredient piroctone olamine, also known as 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone, falls within the scope of Applicants' formula (I) when R^4 = 2,4,4-trimethylpenyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having 1 to 4 carbon atoms) and R^3 = H. Furthermore, Lange discloses, for example, the use of

an anion surfactant, Sodium Lauryl sulphate, in the same phase I composition (e.g., see top of page 15; see also page 16, paragraph 1 wherein piroctone olamine is "substituted" for the zinc pyrithion in that list of ingredients on the top of page 15). Lange does not state that sodium laurel sulphate is an anionic surfactant, but the Examiner contends that sodium laurel sulphate would inherently possess these properties as exemplified by Green People (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant ... which is included as a foaming agent ... in a huge variety of commonly used products ... shampoos").

For ***claim 64***, Lange discloses at least one "additional" surfactant such as lauramide DEA. Lange does explicitly state that "lauramide DEA" is a surfactant, but the Examiner contends that this would be an inherent property of the molecule as exemplified by Aver Skin Care (e.g., see Avre Skin Care, page 10 which discloses "lauramide DEA" as a nonionic surfactant).

Response

12. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "The method of claim 39 and its dependent claims recite administering a sole active component in a single composition. Lange, as the primary reference,

does not anticipate Applicant's claimed invention. Lange requires a two components or two 'phase' shampoo, which is acknowledged by the Examiner. However, it appears that the Examiner may have misunderstood the importance of this aspect of Lange. Lange's two "phases" are separate compositions that must be kept in separate containers. (Lange, p. 11). According to Lange, these two components are used sequentially, never together. One composition (an alkaline anti-mycotic) is used, and then completely rinsed off before the second composition (anti-seborrheic) is used. (Lange, p. 11). Clearly, these are not "phases" in the sense of the aqueous and lipid phases of an emulsion. They are two separate products or compositions, unlike the claimed invention that is a single composition. This fact alone requires that the rejection under 102 be withdrawn." (e.g., see 7/17/06 Response, pages 11 and 12).

[1] The Examiner respectfully disagrees. Applicants set forth a distinction without a difference. A composition that was added "later in time" does not negate the fact that a "single" composition was added first. If this were the case then Applicants' claims would read on situations where patients could never wash their hair again because this "subsequent" application of a composition would qualify as "more than one" composition or, alternatively, could not "reapply" the first composition to continue treatment. That is, if a patient were to apply Applicants' composition in the beginning of the week and then use another shampoo (or medical composition) later in the week, month, year, etc. then this would have to be regarded, according to Applicants, as the use of a "second" composition in violation of the current claims requiring a "single" composition. However, this is an unreasonable interpretation of the claims when viewed in light of the specification (e.g., see Example 8 showing weekly treatments i.e., more than one application of the composition). Here, Lange discloses the use of piroctone olamine

and sodium laurel sulphate in a "single" phase I composition (see rejection above). Therefore, all claimed limitations have been met.

[2] Applicants argue, "The Examiner has cited the Green People and Aver Skin Care documents as secondary references in support of this anticipation rejection. Like the Wikipedia reference discussed above, Applicants question whether one skilled in the art would rely on this particular information because it is less reliable than, for example, information from peer-reviewed texts and information from well-recognized institutions in this field." (e.g., see 7/17/06 Response, page 12, first full paragraph).

[2] As noted above, one of the most highly respected "peer-reviewed" journals stated that Internet sources like Wikipedia are just as accurate as more traditional sources like Britannica (see section [2] above with regard to the Lagarde § 102 rejection). Therefore, Applicants' arguments are moot.

Accordingly, the 35 U.S.C. § 102 rejection cited above is hereby maintained.

Claim Rejections - 35 USC § 103

13. Claims 38-42, 48, 53-58, and 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange (WO 88/00041) (Date of Patent is **14 January 1988**) and FDA (Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis. 56 FR 63568, December 4, 1991, pages 1-3) and Dascalu et al. (WO 96/29045) (Date of Patent is **September 26, 1996**) (of record) as evidenced by Green People (Green People, "Sodium Laurel Sulphate",

2002, page 1, accessed on 12/3/05 at http://www.greenpeople.co.uk/Organics_Features_SLS.htm) and Avre Skin Care (Avre Skin Care, "Dermatology Dictionary", **2002**, pages 1 and 10, accessed on 12/3/05 at http://www.avro.co.za/misc/about_skincare/cosmetic_ingredients.html) and Dreumex (Dreumex, "Dreumex Liquid Soaps", no date, page 1, accessed on 12/3/05 at http://www.signus.com/dsoftsoap.htm) and Odds et al. (U.S. Patent No. 6,514,490) (Date of patent is **February 4, 2003**) and Brinkster (Brinkster, "The pH Scale", page 1, no date, accessed 12/3/05 at http://misterguch.brinkster.net/acidtutorial.html).

For ***claims 39, 41, 42, 56, 57, 62 and 63***, Lange (see entire document) discloses a two phase cleansing, conditioning and medicinal treatment shampoo and methods of use (e.g., see Lange, abstract), which anticipates the claimed invention. For example, Lange discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said shampoo (e.g., see page 12, Example 1, "Shampoo for psoriasis-like seborrhoic dermatitis"; see also page 13, paragraph 1, "The test persons were persons suffering from tenacious dandruff, while one of them suffered from a grave seborrhoeic dermatitis"; see also page 11, first full paragraph, "One may also use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "***The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant*** ... In a specific embodiment ***one may use a water soluble anti-mycotic such as piroctone olamine (Hoechset)***, chemical name 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone"). In addition, Lange discloses at least one 1-hydroxyl-2-pyridone of formula I as the active component (e.g., see Example 2,

especially page 16, paragraph 2 wherein piroctone olamine is substituted for zinc pyrithion as the sole anti-mycotic; see also page 11, first full paragraph; see also page 13, first full paragraph, "One may also [i.e., in addition to phase I] use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics [i.e., piroctone olamine is an anti-mycotic] in the medicinal as well as the anti-dandruff variant ... In a specific embodiment one may use a water soluble anti-mycotic such as piroctone olamine"; see also page 16, first full paragraph, "Similar or even better results were obtained when substituting piroctone olamine for zinc pyrithion [which refers to the "phase I" ingredients of Example 2 i.e., the phase II ingredient don't contain zinc pyrithion for such a substitution to occur]"; see also page 8, last paragraph). The active ingredient piroctone olamine, also known as 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone, falls within the scope of Applicants' formula (I) when R^4 = 2,4,4-trimethylpenyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having 1 to 4 carbon atoms) and R^3 = H. Furthermore, Lange discloses, for example, the use of an anion surfactant, Sodium Lauryl sulphate, in the same composition (e.g., see top of page 15; see also page 16, paragraph 1 wherein piroctone olamine is "substituted" for the zinc pyrithion in that list of ingredients on the top of page 15). Lange does not state that sodium laurel sulphate is an anionic surfactant, but the Examiner contends that sodium laurel sulphate would inherently possess these properties as exemplified by Green People (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant ... which is included as a foaming agent ... in a huge variety of commonly

used products ... shampoos").

For ***claims 48, 58 and 64***, Lange discloses at least one "additional" surfactant such as lauramide DEA. Lange does explicitly state that "lauramide DEA" is a surfactant, but the Examiner contends that this would be an inherent property of the molecule as exemplified by Aver Skin Care (e.g., see Avre Skin Care, page 10 which discloses "lauramide DEA" as a nonionic surfactant).

The prior art teaching of Lange differ from the claimed invention as follows:

For ***claims 38, 53, 65 and 66***, Lange fails to recite the use of a pH range between about 4.5 to about 6.5. Lange only teaches a "neutral" pH (e.g., see Lange, page 6, last paragraph). Although Lange does not define the term "neutral" in terms of a numeric range, the Examiner contends that a pH range between 6-8 is generally considered to be neutral for shampoo products (e.g., see Dreumex, page 1, "Dreumex has developed three types of liquid soaps: Each has a (neutral) pH-value of 6-7; see also Odds et al., column 5, last paragraph "Some of the first active ingredients when at approximately neutral pH (pH 6 to 8)"; see also Brinkster, "Solutions with a pH between 6 and 8 are usually referred to as 'neutral' by nonscientists"). Thus, Lange teaches a pH range that overlaps in scope with the present invention (i.e., pH 6-8 overlaps in scope with a pH of about 4.5 to about 6.5). In addition, Lange teach that lowering the pH to 4-5, using organic acids like lactic acid, do not adversely affect the anti-mycotic action of the 1-hydroxyl-2-pyridones like pirocton olamine (e.g., see page 10, paragraph 2) and provide favorable bacterio and mycostatic properties on their own (e.g., see Lange, page 15, bottom).

For ***claims 40, 55 and 61***, the combined references of Lange and FDA fail to

teach the use of a cyclohexyl radical.

For ***claims 53 and 54***, Lange fails to recite the use of a keratolytic agent.

However, FDA teach the following limitations that are deficient in Lange:

For ***claims 38, 53, 65 and 66***, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. cir. 1990). Here, the pH range disclosed by Lange (pH 6-8 for neutral solutions) overlaps with the claimed about 4.5 to about 6.5 range disclosed by applicant and, as a result, a prima facie case of obviousness has been set forth in accordance with *In re Wertheim* and *In re Woodruff*. Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties (e.g., see *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.). Here, Lange teaches that a pH range of 4-6 can be used in the "phase II" solution (e.g., see page 10, paragraph 2), which indicates that pirocton olamine (which is used in both "phase I" and "phase II") would continue to function as anti-mycotic even at this lower pH range. Thus, a person of skill in the art would expect pirocton olamine to have the same anti-mycotic properties whether it was at a neutral pH (6-8) or a more acidic pH (4-5). In addition, a person of

ordinary skill in the art would have been motivated to adjust the pH to 4-5 using lactic acid because of its favorable bacterio and mycostatic properties (e.g., see Lange, page 15, bottom of page).

For ***claims 40, 55 and 61***, Dascalu et al. (see entire document) teach the use of use of a cyclohexyl radical in the R^4 position (e.g., see claim 4; see also page 3, last paragraph).

For ***claims 53 and 54,*** FDA (see entire document) teaches the use of keratolytic agents like salicylic acid are suitable for topical application in the treatment of seborrheic dermatitis (e.g., see FDA, page 1, Sec. 358.701, page 2, Sec. 358.710, part (b)-(b)(4), "Active ingredients for the control of seborrheic dermatitis ... Salicylic acid, 1.8 to 3 percent").

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use keratolytic agents like salicylic acid in the medicinal treatment shampoo because the FDA explicitly approved this ingredient for its use in treating dandruff and seborrheic dermatitis. Furthermore, one of ordinary skill in the art would have been motivated to use "salicylic acid" as taught by the FDA with the medicinal treatment shampoo as taught by Lange because the FDA states that active ingredients like salicylic acid are "recognized as safe and effective" for treating seborrheic acid. Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because the FDA approved the use keratolytic agents like salicylic acid for the treatment of dandruff and seborrheic dermatitis and also shows its use in conjunction with pyrithion zinc, which is explicitly disclosed as a preferred

embodiment of Lange (e.g., see Lange, Example 2; see also abstract). In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to made to use ciclopiroxolamine in the seborrheic dermatitis treatment described by the combined references of Lange and FDA because Dascalu et al. explicitly states that ciclopiroxolamine is useful for this purpose (e.g., see claims 1 and 4, "A composition for treatment of seborrheic dermatitis of the scalp ... consisting of ... ciclopiroxolamines"). Furthermore, one of ordinary skill in the art would have been motivated to use ciclopiroxolamines as taught by Dascalu et al. because Dascalu et al. teach that these compounds are a "preferred' embodiment (e.g., see claim 4) . Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because Dascalu et al. teach several successful examples of using anti-fungal agents like ciclopiroxolamines (e.g., see claims and examples) and, in addition, it is structurally related to the anti-fungal agents disclosed by the combined references of Lange and the FDA (e.g., 1-hydroxyl-2-pyridones are disclosed in each case).

Response

14. Applicant's arguments directed to the above 35 U.S.C. § 103(a) rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "As discussed in detail above in response to the novelty rejection,

Lange does not suggest such a method, but instead teaches a "two phase" composition that, in effect, is an arrangement of two different compositions at are not compatible, are maintained separately in their packaging, and must be applied sequentially by the user. See Lange Translation cited above and Lange Abstract. For at least this reason, the rejection should be withdrawn." (e.g., see 7/17/06 Response, paragraph bridging pages 12 and 13).

[1] The Examiner respectfully disagrees. Lange discloses the use of piroctone olamine and sodium laurel sulphate in a "single" phase I composition (see rejection above, see also section [1] with regard to the corresponding 35 U.S.C. § 102 rejection).

[2] Applicants argue, "The Examiner has cited Green People, Aver Skin Care, Dreumex, and Brinkster, as secondary references. Applicants note that one skilled in the art would likely not rely on particular information obtained from these websites. This information is less reliable compared to, for example, information from peer-reviewed texts and information from well-recognized institutions in this field (such as the AAD)." (e.g., see 7/17/06 Response, page 13, first full paragraph).

[2] See section [2] in the corresponding 35 U.S.C. § 102 rejection.

[3] Applicants argue, "Moreover, the Examiner has not shown that the cited references would have been combined with Lange to suggest the claimed invention. For at least these reasons, the rejection should be withdrawn" (e.g., see 7/17/06 Response, page 13, first full paragraph).

[3] The Examiner has shown in great detail how Lange anticipates and/or renders obvious

the claimed invention (see rejection above).

[4] Applicants argue, "[a]lthough no prima facie showing of obviousness has been made, Applicants have previously submitted the Declaration of Steve Bradford as evidence of commercial success in support of the patentability of the invention. See papers filed on February 22,2005. The Examiner stated on page 20 of the Office Action that the Declaration was insufficient to overcome the obviousness rejections discussed above. As already discussed, however, the rejections should be withdrawn for other reasons. Moreover, Applicants reserve the opportunity to rely on the information in the Declaration in the future in support of the patentability of the invention without acquiescing in the Examiner's comments in this Office Action" (e.g., see 7/17/06 Response, 2nd full paragraph).

[4] To the extent that Applicants' are merely repeating or preserving their previous arguments, the Examiner contends that those issues were adequately addressed in a previous office action (i.e., page 20).

[5] Applicants further argue, "Nonetheless, in the interests of hastening prosecution, Applicants submit the Declaration of Kevin Kriel, Senior Project Manager at Medicis, who is responsible for the sales and marketing of Loprox Shampoo. His declaration attests to the continued and growing commercial success of Loprox Shampoo. As is clear from Paragraph 1 of the Kriel Declaration, Loprox Shampoo is covered by claims 38, 39, 40, 42, 48, 61, 63 and 64. Further, as Mr. Kriel attests in Paragraph 7, Loprox Shampoo is a composition comprising a 1-hydroxy-2-pyridone (e.g.,ciclopirox), having a pH of 4.5 to 6.5, a surfactant and no additional active compounds. These are the features of the claimed invention and it is this claimed

composition that has continued to grow in sales (up 13%) from January 2005 to January 2006 in a flat or slightly declining market. See Kriel Declaration, Paragraphs 8 and 9. Loprox Shampoo is a prescription shampoo and this continued growth in sales has occurred despite the presence in the market of competitive, mostly less expensive, prescription products. Id., Paragraphs 6 and 7. This 13% increase in market share in an adverse market is an indicator of commercial success and would not have occurred unless physicians and patients judged Loprox Shampoo, even at a premium price, to be a more effective treatment for seborrheic dermatitis than the competitive prescription shampoos already on the market. Id. The continuing increase in market share of Loprox Shampoo, which is FDA approved for the treatment of seborrheic dermatitis, is evidence of commercial success and additional evidence of the non-obviousness of claims 38, 39,40, 42,48, 61 and 63-64. Accordingly, the § 103(a) rejections of the pending claims should be withdrawn." (e.g., see 9/22/06 Supplemental Response, pages 8 and 9; see also Declarations by Kevin Kriel, Todd Plott, and Mitchel S. Wortzman).

[5] The declarations under 37 CFR 1.132 filed on 9/22/06 by Kevin Kriel and/or Todd Plott, and/or Mitchel S. Wortzman are insufficient to overcome the rejection of claims 38-42, 48, 53-58, and 61-66 based upon 35 U.S.C. § 103(a) as set forth above because:

Applicants' arguments are not commensurate in scope with the claims (e.g., see *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims); see also *In re Tiffin and Erdman*, 171 USPQ 294 (CCPA 1971) and cases

cited therein; see also MPEP § 716). In the present case, Kevin Kriel states that ciclopirox, not all of the currently claimed 1-hydroxy-2-pyridones of formula I, has allegedly produced the increase sales (e.g., see Kriel declaration, point 3, "No other ciclopirox shampoo is currently marketed in the U.S. to date."). Thus, the declaration at best only provides support for ciclopirox (i.e., in the Loprox shampoo), not the currently claimed genus of 1-hydroxyl-2-pyridones. Likewise, the Plott and Wortzman declarations also fail to remedy this deficiency. In fact, it is unclear whether the Plott and Wortzman declarations are even being relied on here because Applicants' counsel never mentions these two declarations anywhere their submissions. Furthermore, "there is no evidence showing that such success was attributable to the merits of appellants' invention rather than to other factors such as advertising." *In re Thompson*, 545 F.2d 1290, 192 USPQ 275 (CCPA 1976).

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Accordingly, the 35 U.S.C. § 103(a) rejection cited above is hereby maintained.

Double Patenting

15. Claims 38-42, 48 and 61-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-23 and 26-29 of copending Application No. 10/606,229. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications are drawn to the same treatment of seborrheic dermatitis using the same 1-hydroxyl-2-pyridone compounds having the same generic formula. Thus the applications overlap in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response

16. Applicant's arguments directed to the above double patenting rejection were fully considered but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "Applicants respectfully ask that the Examiner consider the issue of double patenting in the present application only if the co-pending application no. 101606,229 is allowed first. This procedure would ultimately convert the "provisional double patenting rejection" into a "double patenting rejection," and would permit applicants to address the issue of double patenting at that point. To file a terminal disclaimer now, before knowing what scope of claims will ultimately be granted in either application, is premature." (e.g., see 7/17/06 Response, paragraph bridging pages 13 and 14).

[1] While the Examiner agrees with Applicants' logic, that is not the rule and the rejection will not be held in abeyance (e.g., see MPEP § 804 B. Between Copending Applications—Provisional Rejections, "The 'provisional' double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications."). Here, a double patenting rejection is NOT the

only rejection remaining in one of the applications and thus the double patenting rejection is proper.

Accordingly, the double patenting rejection cited above is hereby maintained.

New Rejections

Claims Rejections – 35 U.S.C. 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 38-42, 48 and 61-66 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Verdicchio et al. (EP0117135 A2) (Published August 19, 1984) in view of Janniger et al. (Janniger et al. "Seborrheic Dermatitis" *American Family Physician*, **July 1995**, page 149-155) and Dittmar (U.S. Patent No. 4,185,106) (Date of Patent is January 22, 1980) (of record, e.g., see 6/16/1999 FAOM, withdrawn apparently because the Dittmar reference alone did not teach the claimed pH values). Please note that a 102/103 rejection may is appropriate when the interpretation of the claim(s) is or may be in dispute, i.e., given one interpretation, a rejection under 35 U.S.C. 102 is appro-priate and given another interpretation, a rejection under 35 U.S.C. 103(a) is appropriate. See section MPEP § 706.02(m). Here the term "seborrheic dermatitis" is in dispute (see 35 U.S.C. § 112, second paragraph rejection above).

For ***claims 38 and 39***, Verdicchio et al. (see entire document) disclose a composition for treating dandruff in a human patient (e.g., see abstract and introduction; see also bottom of page 20, "Two groups of 8 people each who have dandruff are compared using each test shampoo twice weekly"). Verdicchio et al. do not explicitly state that these people have seborrheic dermatitis, but the Examiner contends that this is inherently disclosed because dandruff is a form of Seborrheic Dermatitis according to Janniger et al. (e.g., see Janniger et al., abstract, "Seborrheic dermatitis is a common condition that usually appears as simple dandruff."; see also page 149, paragraph 1, "In adolescents and adults, seborrheic dermatitis commonly is manifested as 'dandruff'").

Verdicchio et al. also disclose administering a composition comprises a sole active component which is hydroxy pyridone such as Octopirox. Octopirox falls within the scope of Applicants' formula (I) when R^4 = 2,4,4-trimethylpentyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having 1 to 4 carbon atoms) and R^3 = H (e.g., see page 12, lines 31-34 disclosing the use of octopirox as recited in U.S. Patent No. 4,185,106; see also U.S. Patent No. 4,185,106, claim 3 wherein ethanolamine salt of 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridone (i.e., octopirox) is set forth. Verdicchio et al. also disclose the use at least one surfactant chosen from anionic surfactants cationic surfactants nonionic surfactants and amphoteric surfactants (e.g., see Verdicchio et al., page 20, Examples X and XI showing the use of cocoamido betaine, amidohydroxypropyl phosphobetaine, polyoxyethylene (80) sorbitan laurate, polyethyelen glycol (150) distearate in lines 12-24. Finally, Verdicchio et al. also disclose a pH of "about" and wherein the composition has pH ranging from about to about 4.5 to 6.5 (e.g., see Verdicchio et al., page 20, line 25 showing pH = 6.6, which is "about" 6.5).

For ***claims 40 and 61***, Verdicchio et al. disclose at least one hydroxy pyridone of formula has cyclohexyl radical in the R^4 position (e.g., see Verdicchio et al., page 12, line 32 disclosing the use of compounds set forth in Dittmar i.e., U.S. Patent No. 4,185,106; see also Dittmar, column 1, line 51).

For ***claims 41 and 62***, Verdicchio et al. disclose $CH_2CH(CH_3)CH_2C(CH_3)_3$ in the position in the R4 position (e.g., see Verdicchio et al., page 12, line 32 disclosing the use of compounds set forth in Dittmar i.e., U.S. Patent No. 4,185,106; see also Dittmar, claim

3).

For ***claims 42 and 63***, Verdicchio et al. disclose Octopirox (i.e., 1-hydroxy-4-methyl-6-(2,4,4-trimethylpenty1)-2(H)pyridine (e.g., see Verdicchio et al., page 20, line 22; see also page 12, line 32 disclosing compounds set forth in U.S. Patent No. 4,185,106; see also Dittmar, claim 3).

For ***claims 48 and 64***, Verdicchio et al. method of treating seborrheic dermatitis in human patient in need thereof as claimed in claim 38 in which the composition further comprises at least one additional surfactant chosen from anionic cationic nonionic and amphoteric (e.g., see Verdicchio et al., page 20, wherein cocoamido betaine, amidohydroxypropyl phosphobetaine, polyoxyethylene (80) sorbitan laurate, polyethyelen glycol (150) distearate are disclosed; see also page 5, last paragraph, "The amphoteric surfactants which are useful in the compositions of the present invention include betaines ... phosphobetaines").

For ***claims 65 and 66***, Verdicchio et al. disclose lactic acid to adjust the pH (Verdicchio et al., page 12, line 32 disclosing the use of compounds set forth in Dittmar i.e., U.S. Patent No. 4,185,106; see also Dittmar, column 5, line 47 disclosing the use of "lactic acid" salts).

In the alterative that dandruff is not considered to be the same thing as seborrheic dermatitis as argued by Applicants in direct contrast to the Janniger et al. reference, the claimed treatment would still be prima facie obvious to one of ordinary skill in the art because both dandruff and seborrheic dermatitis are produced by the same causative agent, Pityrosporum ovale, and is generally treated using the same types of medicinal

shampoos (e.g., see Janniger et al., page 152, column 1 disclosing Piyrosporum ovale; see also column 2, Therapy section and Table 2). Thus, even if, for the sake of argument, dandruff could be defined as a "separate" ailment apart from seborrheic dermatitis a person of skill in the art would still expect the same medicinal shampoos to be used in the treatment of both as defined by Janniger et al. Therefore, it would be prima facie obvious to treat the "separate" seborrheic dermatitis condition with a dandruff shampoo like the dandruff shampoo set forth in Verdicchio. One would have a reasonable expectation of success because both are conditions are produced from a common microbe, Pityrosporum ovale organism. In addition, Dittmar et al. explicitly state that their pyridones can be used as "anti-seborrheic agents." (e.g., see Dittmar et al., column 6, line 24). Thus, a person of skill in the art would be motivated to use the "dandruff" compositions to treat both seborrheic dermatitis as well as dandruff. Furthermore, a person of skill in the art would also have reasonably expected to be successful because all reference show the use of medicinal shampoos for the topical treatment of the scalp.

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The

examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
January 20, 2007

JON EPPERSON
PRIMARY EXAMINER